

12. A respiratory suction apparatus according to Claim 11,
wherein the rate of airflow is filtered ambient air and the means
for providing a predetermined rate of airflow further comprising
an opening in the enclosure.

REMARKS

In the Office Action of June 28, 2002, Claims 10-12 were
rejected under 35 U.S.C. Section 112, first paragraph, for
claiming a tether and an occluder. In the present amendment,
applicants have amended Claim 10 to delete reference to a tether
and an occluder and to now call for a flap and a hinge. Support
for these amendments can be found on at least pages 19, lines 1-8
of the specification and at least in Figures 3C and 3D of the
drawings. As such, applicants submit that the amendments to
Claim 10 do not constitute new matter. Applicants have further
removed any reference to an occluder and a tether in Claim 10.
As such, applicants submit that Claims 10-12 do not suffer from
any Section 112 deficiencies, and that the present application
should remain a continuation application.

Also in the Office Action of June 28, 2002, Claims 1-12 were
rejected under 35 U.S.C. Section 112, second paragraph, for being
indefinite. Applicants have amended Claim 1 such that it now
calls for a valve device configured in the adapter to
substantially isolate the catheter from the manifold upon

withdrawing the distal portion of the suction catheter from the manifold. Therefore, applicants respectfully submit that Claims 1-12 do not suffer from any Section 112, second paragraph deficiencies.

Also in the Office Action of June 28, 2002, Claims 1 and 2 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Russo (U.S. Patent No. 5,775,325).

Further, Claims 3-7, 10, and 11 were rejected under 35 U.S.C. Section 102(a) as being unpatentable over Russo.

Additionally, Claim 8 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Russo and further in view of Reynolds (U.S. Patent No. 5,370,610).

Also, Claim 9 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Russo and Reynolds, and further in view of Loescher, et.al. (U.S. Patent No. 5,005,568).

Finally, Claim 12 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Russo and further in view of Reynolds.

Claims 1-12 were also rejected under the judicially created doctrine of Obviousness-Type Double Patenting as being unpatentable over Claims 1-41 of commonly owned U. S. Patent No. 6,227,200.

Applicants respectfully submit that independent Claim 1 as amended defines over Russo. Respectfully, Russo does not

disclose a valve device that is opened by advancement of a suction catheter through the valve device.

Russo discloses a two part closed tracheal suction system that has a valve 27 being present (see Figure 4 of Russo). The valve 27 of Russo is specifically constructed in order to open only when manual depression of buttons 24 and 25 by a user is applied (see column 5, lines 50-56; and column 7, lines 9-16 of Russo). Further, Russo specifically states that the valve 27 will not be opened by the insertion of a suction catheter therethrough (see column 4, lines 37-43 of Russo). As such, Russo discloses a suction catheter system that has a valve that is opened only upon manual depression of buttons next to the valve, and not via insertion of a catheter through the valve. Amended Claim 1 calls for a valve device that is opened by advancement of the suction catheter through the valve device. Such a valve device is clearly not disclosed in Russo which teaches the exact opposite. As such, applicants respectfully submit that independent claim 1 is patentable over Russo.

Therefore, applicants respectfully submit that independent Claim 1 is in proper condition for allowance and that all claims which depend directly or indirectly from independent Claim 1 are also in condition for allowance (Claims 2-9), their rejections being made mute due to the allowance of independent Claim 1.

As stated, independent Claim 10 was rejected in the Office

Action of June 28, 2002, under Section 103(a) as being unpatentable over Russo. Applicants have amended Claim 10 such that it now calls for a valve device where the catheter opens the flap by manual insertion pressure of the catheter on the flap. Such a valve device is not obvious to one skilled in the art upon viewing Russo.

When one skilled in the art views a prior art reference in its entirety, he or she must have some motivation to modify or apply the teachings of the reference in order to solve a problem for the resulting design to be obvious under Section 103(a). Here, when one skilled in the art views Russo, he or she is not motivated to produce a respiratory suction apparatus having a valve device where a catheter opens the flap of the valve device by manual insertion pressure of the catheter on the flap.

Russo seeks to provide a suction catheter system which is comprised of two parts and permits connection and disconnection of a suction catheter assembly without the loss of positive end expiratory pressure (see Russo column 2, lines 32-35). In order to accomplish this, Russo discloses a valve 27 that is located on one component of the two component system (see Figure 6 of Russo). Concerning the valve, Russo states at column 4, lines 37-43:

. . . neither the valve 27 nor its slit 28 can be opened by inserting a relatively soft suction catheter because the present invention uses thick sidewalls 29 and 30 made from firm

75 Sure A Durameter material to keep both valve 27 and sidewalls 29 and 30 in a normally biased closed position.

It is therefore the case that Russo specifically teaches towards a valve 27 that cannot be opened by insertion pressure of a catheter through the valve. In order to allow for the valve to be opened, the suction assembly of Russo is provided with a pair of buttons 24 and 25 which may be depressed in order to open the valve 27 (see Figure 11 of Russo). Russo therefore clearly teaches towards the use of a valve 27 that is not opened by advancement of the suction catheter through the valve device. Specifically, Russo discloses at column 5, lines 51-56:

Advancement of the catheter will not open seal 22 or duct bill valve 27 or slit 28. As illustrated in Figure 7 only manual depression of both buttons 24 and 25 with one hand 56 will open up slit 28 on valve 27 to permit simultaneous advancement of the catheter by other hand 57.

It is therefore the case that Russo teaches one skilled in the art the use of a valve 27 that is opened through external forces and not through the application of insertion pressure by a suction catheter that is advanced by a clinician through the suction catheter assembly.

In stark contrast, independent Claim 10 calls for a valve device where the catheter opens the flap by manual insertion pressure of the catheter on the flap. Such a valve device is

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directly opposite to the one disclosed and taught in Russo. As such, it would not have been obvious to one skilled in the art to modify Russo to attain the valve device of Claim 10 because such modification goes directly against the teachings of Russo. Russo teaches against the use of a valve that may be opened by the insertion of a suction catheter therethrough. As such, it would not have been obvious for one skilled in the art to modify Russo to obtain the suction apparatus as disclosed in Claim 10 because such modification is clearly taught against by the reference. It would not have been obvious to modify a reference in a way that the reference states would produce a device that is inferior.

As such, applicants respectfully submit that independent Claim 10 defines over Russo and is in proper condition for allowance. Also, applicants submit that all claims that depend directly or indirectly from independent Claim 10 are also in condition for allowance (Claims 11 and 12), their rejections being made moot due to the allowance of independent Claim 10.

The other cited references in the Office Action fail to correct for the deficiencies noted in the primary reference of Russo.

In regards to the obviousness-type double patenting rejection of Claims 1-12, applicants are submitting a proper terminal disclaimer from the Assignee of the present application and patent number 6,227,200 that overcomes the double patenting

rejection.

Applicants respectfully submit that all claims are allowable and the application is in condition for allowance. Favorable action thereon is respectfully requested.

The examiner is encouraged to call the undersigned at his convenience to resolve any remaining issues.

Respectfully submitted,

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Amended Claim for U.S. Serial No. 09/716,486 Bal-66-CON (BA00118.4)

1. (Amended) A respiratory suction apparatus comprising:

a suction catheter for removing fluids from a respiratory tract of a patient by insertion of a distal end of the catheter into said respiratory tract and withdrawal of the distal end of the catheter through a portion of said tract while applying negative pressure to a lumen of the catheter;

a protective sleeve surrounding a proximal longitudinal portion of the catheter;

a distal adapter configured for communication with a manifold of a patient's artificial airway;

a collar disposed within the adapter and partially surrounding the distal end of the catheter when the catheter is withdrawn from the manifold, the collar and the catheter defining a substantially uniform cylindrical space around a distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter; and

a valve device configured in the adapter to substantially isolate the catheter from the manifold upon withdrawing the distal portion of the suction catheter [into] from said manifold and applying suction through the catheter lumen, said valve device being opened by advancement of said suction catheter through said valve device.

10. A respiratory suction apparatus comprising:

an elongate suction catheter having a distal end;

a protective sleeve surrounding a proximal portion of the catheter;

a distal adapter configured for communication with a manifold of a patient's artificial airway;

a collar disposed within the adapter and partially surrounding the distal end of the catheter when the catheter is withdrawn from said manifold, the collar and the catheter defining a substantially uniform cylindrical space around a distal portion of the catheter, the cylindrical space capable of directing lavage solution into the adapter;

a cleaning enclosure defined within the adapter wherein the distal end of the catheter is exposed to cleaning liquids and turbulent airflow during a cleaning procedure;

means for providing a predetermined rate of airflow to the enclosure responsive to negative pressure within the catheter;

the catheter being protected at all serviceable times against environmental contamination by a combination of the sleeve, adapter and enclosure; and

a valve device, comprising a flap [an occluder] and a hinge [tether], configured in the adapter whereby the flap [occluder] occludes the catheter responsive to a pressure differential

between said manifold and the enclosure, the catheter opens the flap [occluder] by [responsive to] manual insertion pressure of [on] the catheter, and the hinge [tether] retains the flap [occluder].